K053535

APR 27 2006

Page 1 of 3

SUMMARY OF SAFETY AND EFFECTIVENESS FOR

VivaWave™ Microwave Ablation System

1. Submitter Information

Valleylab, a Division of Tyco Healthcare Group LP
5920 Longbow Drive
Boulder, CO 80301
Contact: Herbert Vinson
Telephone: 303-530-6469

Date summary prepared: December 15, 2005

2. Name of Device

Trade or proprietary Name: VivaWave™ Microwave Ablation System

Common Name: Microware tissue coagulation system

Classification Name and Reference: Class II, 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories, Panel 79, General and Plastic Surgery

3. Predicate Devices

The VivaWave™ Microwave Ablation System is substantially equivalent in function and intended use to the following legally marketed device: Vivant Medical VivaWave™ Microwave System (K011676). The VivaWave™ Microwave Ablation System (this submission) has three (3) or six (6) microwave output channels, each of which produces an output that is essentially identical to the single microwave output in the predicate VivaWave™ Microwave System. Both systems have controls for microwave output power level and procedure (duration) time. Power output is started manually and may be stopped manually with each system. Both systems use microwave antennas with the same performance characteristics to perform ablations. The VivaWave™ Microwave Ablation System has software-based control, whereas the predicate VivaWave™ Microwave System does not. The sizes of the ablations produced by the two systems are similar.

4. Device Description

The VivaWave™ Microwave Ablation System consists of one or two microwave output modules and a pump for circulating cooling fluid, installed in an integrated cart. Each microwave module has three output channels, allowing one, two, or three microwave

antennas (a.k.a. probes, applicators, accessories, or instruments) to be used simultaneously. Multiple antennas may be positioned to ablate separate areas, or placed closer together to produce larger single ablations. Each output channel is limited to 65 watts maximum; a microwave module can power all three channels simultaneously at full power if desired. Systems with two microwave modules have six output channels available for simultaneous use.

Microwave module controls provided to the operator include ablation power and ablation time. All output channels that have an antenna connected operate simultaneously. Each channel receives the same power, corresponding to the power setting on the microwave module front panel. Power delivery is initiated by pushing the Ablate button on the microwave module front panel. Power delivery continues until the duration time setting is reached, or until the Ablate button is pushed again.

The VivaWave™ Microwave Ablation System is designed for use with proprietary microwave antennas such as those cleared for Vivant Medical in submissions K011676 and K032702. (Note: Vivant Medical is owned by Valleylab, a Division of Tyco Healthcare Group LP.) The antennas are connected to the VivaWave System with a proprietary connector incorporating an identification device that allows the microwave module to verify that a correct antenna is attached.

Antennas designed for percutaneous use are cooled internally with sterile saline. They are connected to the VivaWave system cooling fluid pump via sterile tubing. The pump has capacity to supply coolant to six antennas simultaneously if desired. The microwave module monitors coolant temperature within each antenna using an internal thermocouple. Delivery of microwave energy is stopped if an unsafe temperature is reached. Coolant is confined within the antenna and tubing, and does not contact the patient. The pump is controlled by an ON/OFF/Speed Control switch located adjacent to the pump.

Each microwave module can also accommodate up to three proprietary auxiliary temperature probes. (Existing device, refer to K031556.) When auxiliary temperature probes are in use, the temperature at the probe tip is displayed on the microwave module front panel. Auxiliary temperature probes are not required for operation of the VivaWave™ system.

5. **Intended Use**

The VivaWave™ Microwave Ablation System is intended for coagulation (ablation) of soft tissue.

The VivaWave™ Microwave Ablation System is not intended for use in cardiac procedures.

Valleylab recommends against the use of microwave ablation in the following situations:

- Pregnant patients – potential risks to the patient and/or fetus have not been established.
- Patients with implantable pacemakers and other electronic implants. Implanted electronic devices may be adversely affected by microwave power output.

6. **Summary of Technological Characteristics**

The VivaWave™ Microwave Ablation System has the same basic technological characteristics as the predicate device noted above, except that the VivaWave™ Microwave Ablation System has software control.

7. **Performance Data**

Performance testing was performed to ensure that the VivaWave™ Microwave Ablation System functions as intended, and meets design specifications. Sufficient data were obtained to show that the device is substantially equivalent to the predicate device, and meets safety and effectiveness criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2006

Valleylab
c/o Mr. Herbert Vinson
Senior Regulatory Associate
5920 Longbow Drive
Boulder, Colorado 80301-3299

Re: K053535
Trade/Device Name: VivaWave™ Microwave Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NEY, GEI
Dated: March 30, 2006
Received: March 31, 2006

Dear Mr. Vinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

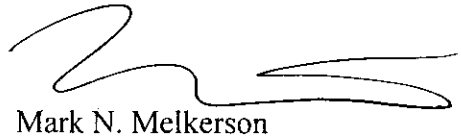
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053535

Device Name: VivaWave™ Microwave Ablation System

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Prescription Use __X__ (21 CFR 801 Subpart D) OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053535